K122581

510(k) Summary

NOV 2 1 2012

Trade Name:	Modified Balloon Guide Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter, 21CFR 870.1250 Class II

Submitter:	Concentric Medical, Inc. 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 650-938-2100 Fax 650-237-5230 Facility Registration #2954917
Contact:	Christina Rowe Manager, Regulatory Affairs

Date Prepared:	November 16, 2012
Predicate Device:	Concentric Balloon Guide Catheter (K112404)

Device Description

Like the predicate device, the Modified Balloon Guide Catheter is a coaxial-lumen, braid-reinforced, variable stiffness catheter designed for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. A radiopaque marker is included on the distal end for angiographic visualization. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. A bifurcated luer hub on the proximal end allows attachments for flushing, inflation and aspiration. Balloon Guide Catheter dimensions and maximum recommended balloon inflation volume are indicated on product label.

Indications for Use

The Indications for Use are the identical to that of the predicate device and are as follows:

> The Modified Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.

Technological Characteristics

The Modified Balloon Guide Catheters have the same technological characteristics as the predicate device. Minor modifications have been made to the device materials and design which were successfully evaluated during verification and validation testing.

Testing Summary

The results of verification and validation conducted on the Modified Balloon Guide Catheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device. Specifically, the following tests were performed on the proposed device and accessories:

- Simulated Use Testing: the ability of the device and accessories to be used per procedural instructions outlined in the Instructions for Use in a neurovascular model was successfully evaluated.
- Balloon Testing: the symmetry and compliance of the distal balloon; balloon inflation and deflation; balloon fatigue strength; constrained balloon burst and leakage were successfully evaluated.
- Tensile Testing: the mechanical integrity of the device under tensile loads was successfully evaluated.
- Tip Deflection Force Testing: the force to deflect the distal tip of the device was successfully evaluated.
- Torque Transmission Testing: the torque transmission ratio was successfully evaluated.
- Leak Testing: the device resistance to leaking during use was successfully evaluated.
- Kink Resistance: the ability of the device shaft to resist kinking was successfully evaluated. .
- Dilator Shape Retention: the shape retention of the dilator tip was successfully evaluated.
- Peel Strength: the force to peel the Peel-Away Sheath was successfully evaluated.

The following biocompatibility tests were performed on the device including the dilator; results for all tests met the pre-determined acceptance criteria.

- Sensitization/Maximization
- Cytotoxicity
- Intracutaenous Reactivity
- Systemic Toxicity/Systemic Injection Test
- Systemic Toxicity/Rabbit Pyrogen Test
- Hemocompatibility/Hemolysis
- Hemocompatibility/Complement Activation
- Hemocompatibility/*in vivo* Thrombogenicity

Summary of Substantial Equivalence

The Modified Balloon Guide Catheter is substantially equivalent to the predicate device with regard to device design, intended use, and patient population. The conclusions drawn from the verification and validation testing conducted using the Modified Balloon Guide Catheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 21, 2012

Concentric Medical, Inc.
c/o Ms. Kirsten Valley
Manager of Regulatory Affairs
301 East Evelyn Ave.
Mountain View, CA 94041

Re: K122581
Trade/Device Name: Concentric Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 9, 2012
Received: October 10, 2012

Dear Ms. Valley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang

for

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122581

Device Name: Concentric Balloon Guide Catheter

Indications For Use:

The Concentric Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for retrieval devices.

Prescription Use XX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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